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10/773,775	02/05/2004	Shuqi Chen	IQA-009.01	7895

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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/773,775	CHEN ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-10,14-18,23-32,36,37,44,45,47-49,52-80 and 85-93* is/are pending in the application.

4a) Of the above claim(s) *48,49 and 52-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-10, 14-18, 23-32, 36-37, 44-45, 47, 76-80, 85-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 1, 6, 9, 10, 14, 21, 49, 52, 86-88, and 91 is acknowledged and has been entered.

2. Applicant's addition of claims 92-93 is acknowledged and has been entered.

3. Applicant's cancellation of claim 5 is acknowledged and has been entered.

4. Claims 1-4, 6-10, 14-18, 23-32, 36-37, 44-45, 47, 76-80, 85-93 are currently under examination.

5. Claims 48, 49, 52-75 are withdrawn.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 92 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 92 recites the limitation "a segment" in the first line. There is insufficient antecedent basis for this limitation in the claim. In particular, it is unclear if which segment "a segment" would refer to or if it refers to an additional segment that was not previously recited.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-4, 6-10, 14—17, 29-30, 32, 36, 37, 44, 45, 47, 76-80, 85-89, 90-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryning et al. [US 7,198,759] in view of Dimond et al. [US 2002/0192677].

With respect to claims 1, 47, Bryning et al. teach a substrate that may be card shaped (column 6, lines 24-30) and comprise a linear series of multiple chambers that can each independently be loaded with a reactant, agent, solution, or other material, or be provided with filtration media and/or frits (column 10, lines 33-65) which may be used for PCR amplification reactions of nucleic acids (column 10, line 65 – column 11, line 2). Bryning et al. further teach that that the chambers may be separated by intermediate inelastically deformable walls and elastically deformable cover layers (column 9, lines 3-40), that allow for fluid transfers between two or more recesses that can be made in communication by deformation of the intermediate wall (column 7, lines 25-47), wherein fluid samples may move from one chamber to subsequent reagent containing chambers (column 16, lines 25-30). Bryning et al., however, do not specify that the first segment contains a substance capable of specific binding to a preselected component of a sample, that the second segment contains a wash reagent, and that the third reagent contains an amplification reagent.

Dimond et al., however, teach that PCR reactions can be performed by immobilizing target DNA to magnetic particles (para. 0252), followed by washing and then addition of ligation/amplification buffer (para. 0252).

Therefore, it would have been obvious to have included a substance capable of binding to a specific component in a sample, a wash reagent, and an amplification reagent in a sequential set of chambers, so that the PCR amplification process as taught by Dimond et al. could be performed in the device of Bryning et al.

10. With respect to claim 2, Bryning et al. teach that the substrate may comprise glass, which would be transparent (column 7, lines 5-20).

11. With respect to claim 3, Bryning et al. teach that the fluid can be moved through the series of chambers by a pressure differential generated (column 16, lines 40-60). Therefore, the deformable walls taught by Bryning et al. as discussed above would act as pressure gates.

12. With respect to claim 4, Bryning et al. teach a chamber that can be loaded with filtration media and/or frits (column 10, lines 33-65).

13. With respect to claim 6, Bryning et al. teach target analytes comprising nucleic acids (column 10, line 65 – column 11, line 2).

14. With respect to claims 7-10, as discussed above, Dimond et al. teach immobilizing target DNA to particles by using covalently attached oligonucleotides (para. 0252) that have specific preselected sequences (para. 0251).

15. With respect to claims 14-15, Dimond et al. teach immobilizing target DNA to particles by using covalently attached oligonucleotides (para. 0252).

16. With respect to claims 16, 17, Dimond et al. teach magnetic particles (para. 0252).

17. With respect to claim 29, 30, Bryning et al. teach that the chambers may be located within a frame such as an assembly and resting on a support in a microfluidic manipulation system (column 17, lines 16-41), wherein the system may be used to introduce a sample into the first chamber (fig. 14, column 16, lines 9-40).

18. With respect to claim 32, Dimond et al. further teach that the assay may further involve a DNA ligase (para. 0252).

19. With respect to claims 36, 37, Bryning et al. further teach that that the chambers may be separated by intermediate inelastically deformable walls and elastically deformable cover layers (column 9, lines 3-40), which act as peelable seals (see also Figs 1b-3b).

20. With respect to claims 44, 45, Bryning et al. teach a linear series of multiple chambers that can each independently be loaded with a reactant, agent, solution, or other material, or be provided with filtration media and/or frits (column 10, lines 33-65), which would constitute a linear and contiguous array.

21. With respect to claim 76, Bryning et al. teach that the reagents may comprise dry reagents (column 16, lines 40-45).

22. With respect to claim 77, Bryning et al. teach that the intermediate wall can remain partially deformed for at least 50 seconds or can be permanently deformable to enable fluid transfer between two chambers (column 7, lines 26-48). Therefore after bursting, the surface between the two chambers would be substantially free of obstructions to fluid flow.

23. With respect to claims 78-80, Bryning et al. teach a linear series of multiple chambers that can each independently be loaded with a reactant, agent, solution, or other material, or be

provided with filtration media and/or frits (column 10, lines 33-65), which would constitute a linear and contiguous array.

24. With respect to claim 85, 88, Dimond et al. teach that the samples may be diluted prior to amplification (para. 0223-225), and that unhybridized probes may be eluted after hybridization (para. 0244). Therefore it would have been obvious for a diluent to be included in a segment prior to the first segment to dilute and prepare the sample for amplification and a segment containing a elution reagent after the third segment, in order to separate unhybridized reactants from the product.

25. With respect to claims 86, 89, Dimond et al. further teach the addition of a stop reagent (neutralization reagent) after amplification of the sample (para. 0252). Therefore, it would have been obvious to one of ordinary skill in the art to have included a stop reagent in a fourth chamber distal to the other chambers in order to end the amplification reaction after a predetermined amount of time.

26. With respect to claim 87, Dimond et al. teach labeling the products of amplification with a labeling probe (para. 0253). Therefore, it would have been obvious to one of ordinary skill in the art to have included a detection reagent such as a labeling probe in a fourth chamber distal to the other chambers in order to detect the products of the amplification reaction after a predetermined amount of time.

27. With respect to claim 90, Dimond et al. teach that the amplification reagent may comprise a nucleic acid polymerase (para. 0242).

28. With respect to claims 91, 93, Dimond et al. teach immobilizing target DNA to particles by using covalently attached oligonucleotides (para. 0252).

29. With respect to claim 92, Bryning et al. teach a indicator solution (column 17, lines 5-16).

30. Claim 18 is rejected 35 U.S.C. 103(a) as being unpatentable over Dimond et al. [US 2002/0192677] in view of Bryning et al. [US 7,198,759], as applied to claim 14 above, and further in view of Presnell et al. [US 2003/0134390].

With respect to claims 4, 17, 18, Chen et al. teach the use of beads, but fail to teach the use of filters or silica beads.

Presnell et al., however, teach the use of silica beads, and further teach that these commercially available, and are methods for binding receptors to the beads are well known in the art (para. 0086). Presnell et al. further teach that the beads can be used for purifying samples, thus acting as a filter (para. 0142).

Therefore, one of ordinary skill in the art at the time of the invention would have been motivated to use silica beads in the device of Chen et al., and further to use them as filters, as suggested by Presnell et al., in order to more easily produce the device of Chen et al. by using resources commonly available at the time, and also to obtain better data by purifying the sample.

31. Claims 23-28, 31 are rejected 35 U.S.C. 103(a) as being unpatentable over Bryning et al. [US 7,198,759] in view of Dimond et al. [US 2002/0192677], as applied to claim 14 above, and further in view of Glezer et al. [US 2004/0189311].

With respect to claims 23, 31, Bryning et al. teach that the chambers may be located within a frame such as an assembly and resting on a support in a microfluidic manipulation system (column 17, lines 16-41), wherein the system may be used to introduce a sample into a

first chamber (fig. 14, column 16, lines 9-40). Bryning et al. fail to teach a cap for closing the open end comprising a sample collection device.

Glezer et al., however, teach sample chambers defined within cartridge that are adapted and configured to receive a modular detachable insert that includes a cap for sealing the chamber (para. 0182). Glezer et al. further teach that this insert within the sample chamber allows for independent selection of materials for the main cartridge body, and allows for sealing the sample introduction port and prevents leakage of the sample and possible exposure of the user or associated instruments to biohazards (para. 0182).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included a cap in the system of Bryning et al. in order to provide independent selection of materials for the main cartridge body, and to seal the sample introduction port, thus preventing leakage of the sample and possible exposure of the user or associated instruments to biohazards.

With respect to claims 24, 25, Glezer et al. further teach that the cap may comprise a sample collection device such as a swab (fig. 30), which would transfer a sample to the chambers while also keeping the open end closed.

With respect to claim 26, Glezer et al. teach that the cap helps form a sample chamber (para. 0184, fig. 27), thus defining a cavity within the device (fig. 27).

With respect to claim 27, Glezer et al. teach that the cap may comprise an elastomeric material (para. 0185), which would be expandable.

With respect to claim 28, Glezer et al. teach that the cap can be used to seal the introduction ports without preventing flow of air through the vent conduits (para. 0184), wherein the cap mechanism may also comprise a removable piercing/venting mechanism (para. 0185).

32. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. [US 5,422,271] in view of Miethe et al. [US 6,488,894].

With respect to claim 47, Chen et al. teach a device for amplifying and detecting nucleic acid material comprising a reaction compartment for amplifying a sample of nucleic acid material, a detection site for detecting amplified nucleic acid material (column 2, lines 34-52). Chen et al. further teach compartments with passageways that remain sealed, comprising three reagent compartments (column 3, lines 55-65), the compartments comprising wash solution (column 4, lines 29, 30), reagents need for PCR amplification (column 4, lines 2-5), compartments comprising members of a binding pair (column 4, lines 8-11), second wash solutions (elution buffer) (column 9, lines 65-67), dilution buffers (column 9, lines 50-52). Furthermore, in the arrangement disclosed by Chen et al., the segments are arranged such that the distal ends of the segments are located at the distal ends of the other segments. Chen et al., however, fail to teach that the segments for a substantially linear array.

Miethe et al., however, teach a device comprising a segregated reagent column (column 2, lines 38-55) comprising chambers in a linear, contiguous array (fig. 1-3) and further teaches that this allows for a precise, chronologically defined and sequential discharge of different reagents without prior mixing of the reagents in a simple manner (column 2, lines 31-45).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the segments of Chen et al. to be arranged in a substantially linear array, as suggested by Miethe et al., in order to allow for a precise, chronologically defined and sequential discharge of different reagents without prior mixing of the reagents in a simple manner.

Response to Arguments

33. Applicant's arguments with respect to claims 1-4, 6-10, 14-18, 23-32, 36-37, 44-47, 76-80, 85-93 have been considered but are moot in view of the new ground(s) of rejection.

34. It is noted that applicant's arguments with respect to claim 47 is not found persuasive, as the claim does not recite the order of the segments.

Conclusion

35. No claims are allowed.

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571)272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

37. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/
Patent Examiner, Art Unit 1641